accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing that the new drug is "bioequivalent" to an approved drug. 21 U.S.C. 355(j). It also encourages the development of generic drugs by declaring various research and development activities non-infringing. 35 U.S.C. 271(e)(1); see *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237, 125 S. Ct. 2372 (June 13, 2005).

The Act's incentive structure to accelerate the introduction of generic drugs begins with the requirement that the branded firm submit to the FDA a list of all patents that the firm claims cover its drug. 21 U.S.C. 355(b)(1). A generic firm submitting an ANDA must make a certification regarding the application of any listed patent to its product. Most pertinent here, a so-called "Paragraph IV certification" states that the patent is invalid or not infringed, and thus clearly identifies a patent dispute. 21 U.S.C. 355(j)(2)(A)(vii)(IV). Congress sought to encourage patent challenges by providing that the first generic applicant filing a Paragraph IV certification would obtain 180 days of marketing exclusivity. 21 U.S.C. 355(j)(5)(B)(iv). No parallel economic incentive is provided for ANDA filings that do not challenge the branded drug's patent. Congress likewise created an economic incentive for the patent holder to commence suit upon receiving a Paragraph IV notification. Upon receipt of notice from an ANDA filer, the patent holder receives an automatic 30-month stay prohibiting generic entry into the market, if it sues the generic for infringement within 45 days. 21 U.S.C. 355(j)(5)(B)(iii). If such litigation is not commenced within 45 days, however, the FDA approval process may proceed, and the FDA may approve the ANDA as soon as regulatory requirements are fulfilled. *Ibid.*

As reflected in the instant case, the parties to such litigation can use settlements to carve up the market between them to avoid the risks of competition. There is no indication, however, that Congress meant to pre-empt the application of settled

antitrust principles to such settlements. Indeed, prompted in substantial part by congressional concern over the competitive effects of agreements such as those at issue here, Congress amended the Hatch-Waxman Act as part of the 2003 Medicare Amendments, *supra*. Those amendments sought in part to stamp out the "abuse of the Hatch-Waxman law" resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market." S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002). In the words of Rep. Waxman, "[t]he law has been turned on its head. * * * We were trying to encourage more generics and through different business arrangements, the reverse has happened." Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, The New York Times, July 23, 2000, at A11 (quoting Rep. Waxman). Among the various corrective measures to address such abuses, the amendments require pioneer drug companies and generic applicants who enter into patent litigation settlements to file those settlement agreements with the Commission and the Department of Justice for antitrust review. Pub. L. No. 108-173, §§ 1111-1118 (Pet. App. 360a-363a). In the event that such an agreement is found to violate the antitrust laws, the amendments provide that the generic party will forfeit any 180-day marketing exclusivity period it may have. 21 U.S.C. 355(j)(5)(D)(i)(V).

Experience has borne out the efficacy of this congressional scheme and the correctness of its premises – *i.e.*, that many patents will not stand in the way of generic entry if challenged, and that successful challenges can yield enormous benefits to consumers. The Commission studied all patent litigations initiated between 1992 and 2000 between branded drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 19-20

(July 2002), <www.ftc.gov/os/2002/07/genericdrugstudy.pdf> ("*FTC Generic Drug Study*"). Generic competition following successful patent challenges to Prozac, Zantac, Taxol, and Plantinol alone is estimated to have saved consumers more than $9 billion.[2] These savings result from the pricing policies of generic sellers, which generally price at a substantial discount from branded drugs. As a result of such price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, branded drugs lose an average of 44 percent of their sales within the first full year after launch of a lower-priced generic product.[3]

2. Respondent Schering-Plough Corp. ("Schering") markets "K-Dur 20," a potassium supplement generally taken in conjunction with drugs for high blood pressure or congestive heart disease. See Pet. App. 2a-4a, 48a-52a. At the time of the subject agreements, K-Dur 20 was the most frequently prescribed potassium supplement, with annual sales reaching $170 million by 1997. The active ingredient in K-Dur 20, potassium chloride, is in common use and is unpatentable. Schering owns a formulation patent ("the '743 patent") that relates to the material that coats the potassium chloride crystals, providing an extended-release mechanism. The '743 patent expires in 2006. Thus, a generic manufacturer can use the active ingredient in K-Dur 20 without infringing Schering's patent, so long as it uses a coating material not covered by the '743 patent.

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[2] *Generic Pharmaceuticals Marketplace Access and Consumer Issues. Hearing Before the Senate Commerce Comm.*, 107th Cong. (April 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, <http://commerce.senate.gov/hearings/042302jaegar.pdf>.

[3] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xiii (July 1998) ("*CBO Study*").

In 1995, two generic drug makers, ESI Lederle Inc. ("ESI") and respondent Upsher-Smith Laboratories, Inc. ("Upsher"), filed ANDAs for approval of generic versions of K-Dur 20, both with Paragraph IV certifications that the products they intended to market in direct competition with K-Dur 20 were non-infringing generic substitutes. Schering brought separate patent actions against ESI and Upsher, each within the respective 45-day period so as to trigger the 30-month automatic stay of FDA approval.

In late 1996, Schering and ESI began settlement negotiations. In March 1997, ESI proposed that Schering make a payment to ESI, in return for which ESI would delay its market entry. Pet. App. 251a-252a. The parties eventually reached such a settlement. *Id.* at 52a. A portion of the settlement covered a side deal for various product licenses, but it is undisputed that, separately, Schering agreed to pay ESI $15 million not to market any generic version of Schering's K-Dur 20 before January 2004. *Id.* at 142a n.101. Of that amount, $10 million had no proffered rationale other than warding off competition by ESI; ESI would receive it only if FDA approved ESI's application to sell its generic drug. *Ibid.* ESI ultimately obtained FDA approval, and Schering made the additional $10 million payment *Ibid.*

Two months after it began its settlement negotiations with ESI, Schering entered into settlement negotiations with Upsher. *Id.* at 97a. From the very first negotiating meeting, Upsher made a demand of $60-70 million from Schering to stay off the market. *Ibid.* On the eve of trial, Schering and Upsher entered into an agreement that settled their patent litigation. *Id.* at 50a. Schering agreed to make the unconditional, up-front $60 million payment Upsher had demanded, and Upsher agreed to forego marketing its generic product until September 2001. *Ibid.* Upsher also agreed to grant Schering a license to market six Upsher products in prescribed territories, with conventional royalties tied to the actual sales of those products. *Ibid.* The

$60 million unconditional payments were justified to Schering's board of directors as a "prerequisite of any deal" and as dictated by Upsher's desire for a guaranteed income stream to compensate it for lost revenue it otherwise would have earned from the generic potassium product. *Id.* at 97a n.78.

As a result of these agreements, Upsher and ESI remained off the market until 2001 and 2004, respectively, contrary to the parties' own prior expectations.[4] Market changes that occurred upon entry reflect the impact of the delayed entry. Upsher entered the market at a price approximately 50 percent of the price of K-Dur 20. Total branded Schering prescriptions fell from roughly 1,150,000 to approximately 390,000 within twelve months, and the lost 760,000 prescriptions were almost completely offset by sales of approximately 700,000 prescriptions of generic K-Dur. Pet. App. 72a-73a. Consumers thus saved many tens of millions of dollars in lower drug prices the first year after generic entry.

3. The Commission issued its administrative complaint in March 2001, charging that Schering's agreements with Upsher and ESI violated section 5 of the FTC Act, 15 U.S.C. 45. ESI entered into a consent agreement in April 2002, but respondents proceeded to trial; Schering sought to defend both agreements. An administrative law judge ("ALJ") dismissed the complaint in June 2002. Pet. App. 160a. The Commission reversed in December 2003, concluding on *de novo* review that the ALJ erred in several key factual findings and in his legal analysis.

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[4] Pre-settlement Schering documents showed that Schering had expected that generic entry would substantially erode its K-Dur 20 sales in 1998 and 1999. Pet. App. 69a. Upsher had similarly projected generic entry and lower prices starting in 1997, *id.* at 70a, and had informed the patent court in March 1997, after receiving tentative FDA approval, that the statutory stay on final approval was the only impediment to its immediate entry. *Id.* at 86a.

The Commission first determined that per se condemnation was not warranted, given the complexities of the patent litigation context in which the agreements arose. Pet. App. 60a-62a. Nevertheless, it concluded that the issue of market power could be addressed by direct proof of the effects of the introduction of generic K-Dur 20. *Id.* at 65a-67a (citing *IFD*, 476 U.S. at 460-461). The Commission found that there was abundant evidence that generic entry here was a "uniquely significant market event" that lowered prices and took substantial sales away from Schering, and therefore that delaying such entry had actual anticompetitive effects. *Id.* at 68a-75a.

The Commission then considered the exclusionary impact of the agreements in relation to that of the patent itself. It began with the observation that the strength of a patent does not depend simply on its expiration date, but on the probability that litigation will or will not prove the patent to be valid or, in this case, infringed. *Id.* at 81a-82a. Therefore, a hypothetical settlement in which the parties compromised on a time of entry without cash payments would reflect the strength of the patent as viewed by the parties. *Id.* at 75a-76a. The Commission further recognized, however, that Schering would not have made the large cash payments in this case without some *quid pro quo* and, in the absence of other consideration, it is logical to conclude that Schering was buying protection from the competition that could have resulted from the litigation. *Id.* at 76a-77a. The Commission found further support for this conclusion in the language of the settlement agreement and in the bargaining history – which, as noted above, began with Upsher's demand for a large cash payment. *Id.* at 77a. The Commission also considered whether a direct examination of the patent issues would be a better way to take account of the patent dispute in antitrust analysis, but concluded that such an inquiry was neither necessary nor appropriate here. *Id.* at 80a-

87a.[5] As the final step in its analysis, the Commission acknowledged that certain procompetitive effects of the agreements were "theoretically possible," *id.* at 61a, but found no evidence that those theories applied. *Id.* at 87a-92a.

With respect to the Upsher agreement, the Commission addressed in detail and rejected respondents' contention that the $60 million payment was entirely for side licenses conveyed under the agreement and not for Upsher's promise to delay its entry. Pet. App. 92a-141a. It found that the evidence demonstrated that the amount and unconditional nature of Schering's payment were based on Upsher's demand that it be compensated for its anticipated lost revenues during its absence from the market. *Id.* at 94a-107a. The Commission also rejected Schering's argument that one of the Upsher licences itself warranted the $60 million payment, finding that Schering's purported assessment of the Upsher product was belied by its own contemporaneous assessment of a similar product offered by a company that did not threaten it with generic competition.[6]

Schering's agreement with ESI evidenced on its face a promise to defer entry in exchange for cash payments. *Id.* at 142a. On those undisputed facts, and following the same

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[5] Although FTC staff argued that a post hoc adjudication of the underlying patent cases was unwarranted, it nonetheless also introduced evidence in support of the proposition that Schering faced a substantial risk that Upsher and ESI would be found not to infringe. Contrary to the court's assertion, however, the ALJ did not "evaluate[] the strength of the patent" (Pet. App. 15a), concluding that "the likely outcome of the patent disputes cannot be reliably predicted." *Id.* at 312a. He relied instead on an erroneous presumption of infringement. See *Id.* at 81a n.60.

[6] The Commission found Schering's product review perfunctory and not consistent with what Schering required in the past to evaluate a similar commercial opportunity. Pet. App. 108a-130a. Moreover, a more thorough and contemporaneous Schering analysis of a comparable product demonstrated that Schering in fact thought that those products did not justify a substantial, non-contingent payment. *Id.* at 111a-117a.

analytical approach it applied to the Upsher agreement, the Commission concluded that this agreement was an unreasonable restraint of trade. *Id.* at 142a-145a.

4. On Schering's and Upsher's petitions for review, the court of appeals set aside the Commission's decision. *Id.* at 2a. The court began with the startling premise that "neither the rule of reason nor the *per se* analysis is appropriate" in an antitrust case involving patents, and that the analysis must instead focus on the "exclusionary potential" of the patent, and whether the agreements had exceeded that potential. *Id.* at 16a-17a (citing *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied sub nom. Walgreen Co.* v. *Abbott Labs.*, No. 03-1178 (Oct. 12, 2004)). In assessing the exclusionary potential of the '743 patent, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and ESI from the market until they proved either that the * * * patent was invalid or that their products * * * did not infringe Schering's patent," *id.* at 18a, and noted that there was no allegation that the patent claim was a "sham." *Id.* at 20a.

In particular, the court ruled that a payment by the patentee, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger must have agreed to a later date in return for such payment, even if there was no other plausible explanation for the payment. In the case of the ESI agreement, for example, the court held that the $10 million payment that was directly linked to regulatory approval of the generic drug and for which no other consideration was attributed was lawful because it was "within the patent's exclusionary power." *Id.* at 28a. The court also cited, as to both agreements, the presumed public policy benefits of the settlement of litigation. *Id.* at 28a-29a. The court concluded that the existence or size of such a payment cannot be used to show that the patent holder has obtained a greater degree of market exclusion than its patent justified. *Id.* at 35a.

Despite these legal holdings, the court of appeals nevertheless reviewed and rejected the Commission's extensive factual findings in support of its conclusion that Schering had paid Upsher for delayed entry. *Id.* at 21a-26a. The court was particularly critical of the Commission's decision not to accept the "credibility" determinations of the ALJ (*id.* at 25a-26a), but declined to address the Commission's stated reasons for reaching its conclusions. *Cf. id.* at 94a-96a. The court of appeals criticized the Commission for taking the economic incentives of the parties into account in assessing the plausibility of their claims that the side deal itself warranted the $60 million payment. *Id.* at 23a-25a. The court referred to "overwhelming" evidence in support of the ALJ's findings (*id.* at 25a, 26a), but did not identify any such evidence.

REASONS FOR GRANTING THE PETITION

This case merits review by this Court to correct fundamental legal errors by the court of appeals that not only depart from settled antitrust and administrative law principles, but also dramatically alter Congress's intended balance between the patent and antitrust laws as applied to generic drugs. Contrary to this Court's teachings, the court of appeals' ruling essentially imposes a rule that a patentee is presumptively entitled to buy protection from all competition for the full patent term, even if such payments effectively augment the patent's actual exclusionary power. To fashion this rule, the court candidly stated that, to resolve this antitrust case, it would apply "neither the rule of reason nor the per se analysis" but would reach a result that "reflects policy." Whatever the source of that policy, it cannot be found in the Patent Act, which recognizes that infringement is not to be presumed but proven by the patentee; the Hatch-Waxman Act, which seeks to stimulate generic challenges to branded drugs; or the antitrust laws, which

prevent monopolists from buying off would-be rivals by the simple device of sharing monopoly profits with them.

Review of this error is urgently needed because the ruling below could seriously impede the Commission's law enforcement efforts on behalf of consumers nationwide. In light of the large number of leading drugs that are the subject of patent challenges, the economic stakes for the American consumer in this issue are staggering.

The court of appeals' reversal of the Commission's factual findings regarding the Upsher agreement also warrants review, because it departs so drastically from the established standard of appellate review. This issue does not, however, affect the court of appeals' analysis of the ESI agreement, which independently warrants the grant of *certiorari* on Question 1.

I. THE COURT OF APPEALS ERRED IN RULING THAT AGREEMENTS BETWEEN COMPETITORS ARE LAWFUL IF WITHIN THE "POTENTIAL" REACH OF A PATENT CLAIM.

1. The starting point for this case, as the court of appeals recognized, is that an agreement between competitors in which one pays the other to stay out of a market is "clearly anticompetitive," and hence unlawful unless excused by the lawful exercise of patent rights. Pet. App. 13a. This Court has repeatedly dealt with analogous situations. See, *e.g.*, *United States* v. *Masonite Corp.*, 316 U.S. 265, 274 (1942); *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436, 455 (1940). In such cases, the overarching principle is clearly established: that "[t]he owner of a patent cannot extend his statutory grant by contract or agreement." *Masonite*, 316 U.S. at 277; *Ethyl*, 309 U.S. at 456; *United States* v. *Line Material Co.*, 333 U.S. 287, 308 (1948), even if the agreement takes the form of a litigation settlement. See *United States* v. *Singer Mfg. Co.*, 374 U.S. 174, 197-200 (1963) (White, J., concurring) (competitors' collusive

termination of a patent interference proceeding to help broaden the patent's scope runs afoul of the Sherman Act). Although the court of appeals acknowledged this principle, Pet. App. 18a, it failed to appreciate that parties settling litigation deal in uncertainties, and that the elimination of the prospect of competition, even if uncertain, harms consumers. The standard the court set down gives patentees free rein to "buy off" potential competitors, even in the context of generic drugs, where Congress has specifically sought to promote patent challenges to facilitate non-infringing generic entry.

The sweeping nature of the court of appeals' rule derives from its approach to assessing the "exclusionary potential of the patent." Pet App. 17a. The court based its reasoning upon the statutory presumption of patent validity, 35 U.S.C. 282, and upon a demonstrably *incorrect* extension of that presumption to the patent infringement issues most relevant here,[7] and ruled that the "exclusionary power" of the patent at issue here encompassed a right to exclude both Upsher and ESI from the market "until they proved either that the '743 patent was invalid or that their products * * * did not infringe Schering's patent." Pet. App. 18a. Although the court appeared to acknowledge that the presumptions it relied upon could be overcome by "evidence to the contrary," *id.* at 20a, the only circumstance in which it indicated the parties would exceed the exclusionary potential of the patent was that of "sham" infringement claims. *Ibid.* Furthermore, in light of the same court's earlier ruling that an exclusionary settlement could not be condemned "merely because the patent is subsequently declared invalid," in the absence of a showing such as that the

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[7] The Federal Circuit has consistently held that the patent holder has the burden of proving infringement by a preponderance of the evidence. See, *e.g.*, *Kegel Co., Inc.* v. *AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997); *Wolverine World Wide, Inc.* v. *Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994).

patentee "knew" that the patent was invalid or not infringed, *Valley Drug*, 344 F.3d at 1306, 1308-1309, it appears that the court below would recognize only limited exceptions to its rule that settlements within the outer, nominal bounds of patent claims are presumed lawful.

The court of appeals' formalistic approach to the issue of the "exclusionary potential" of the patent ignores the most salient factor that gives rise to patent litigation and settlements, the existence of *uncertainty* regarding whether a patent is valid, or (as was the focus here) infringed by particular products. Upsher and ESI stood as potential competitors to Schering's K-Dur; they could offer competing products unless Schering demonstrated that their products infringed. It is a fundamental principle of antitrust law, however, that it is unlawful to enter into an agreement in which potential competitors (even those whose successful entry is uncertain) agree to stay out of a market. See *Palmer* v. *BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam).[8] "[T]he anti-trust laws are as much violated by the prevention of competition as by its destruction." *United States* v. *Griffith*, 334 U.S. 100, 107 (1948) (citation omitted); see also *United States* v. *Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) ("it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash

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[8] In that case, the court of appeals had accepted the view that the agreement of one party (BRG) not to enter into the bar review business outside of the state of Georgia could not be condemned as a market allocation agreement, because "BRG had never done business outside the state of Georgia, [and] nothing in the record suggested that it ever intended to do so * * *." 874 F.2d 1417, 1424 (11th Cir. 1989). This Court rejected that reasoning, holding that "[s]uch agreements are anticompetitive regardless of whether the parties split a market within which both do business * * *." 498 U.S. at 49-50. As one leading commentator has put it, citing *Palmer*, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." XII Herbert Hovenkamp, *Antitrust Law*, ¶ 2030b, at 175 (1999).

nascent, albeit unproven, competitors at will"). Had Schering paid substantial sums of money to a potential generic to delay entry, where the only impediment to entry was uncertainty about the generic's ability to obtain FDA approval, there would be no question that such an agreement was anticompetitive. See *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799, 806-809 (D.C. Cir. 2001) (uncertainty of FDA approval does not preclude antitrust claim). There is no reason why uncertainty regarding patent litigation should be treated differently.

Although all property rights are subject to legal uncertainties, the "probabilistic" nature of the property interest created by the patent laws[9] makes it especially important to take such uncertainty into account. Unlike forms of property that are defined in terms of title to tangible items with clearly defined boundaries, the exercise of rights conferred even by a valid patent requires that the boundaries of the patent's coverage be delimited in relation to an accused infringing product. "The heart of [a patentee's] legal monopoly is *the right to invoke the State's power* to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp.* v. *Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (emphasis added). When it asserts its patent and threatens a lawsuit, the patentee can hope that the strength of its patent will either convince the accused infringer to accede or convince a court to issue an injunction, but neither path guarantees success. As both economists and legal scholars have remarked, "a patent is not a right to exclude, but rather a right to *try* to exclude."[10]

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[9] See Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Perspectives 75 (2005); Carl Shapiro, *Antitrust limits to patent settlements*, 34 RAND J. Econ. 391, 395 (2003).

[10] Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1761 (2003) (emphasis added); see Shapiro, *supra* note 9, at 395.

Available empirical data reinforce the importance of taking such uncertainties into account in any practical assessment of the "exclusionary potential" of a patent claim. A study examining nearly all written, final validity decisions by the district courts and the Federal Circuit from 1989 through 1996 found that 46 percent of patents challenged in litigation were invalidated. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-206 (1998). As discussed above, the percentage of vulnerable patent claims appears to be even greater in the Hatch-Waxman context, in which branded companies have often aggressively made multiple patent claims for drugs facing generic challenge. See *FTC Generic Drug Study* at 19-20.

2. Accordingly, a realistic assessment of whether a patentee settling a disputed claim has "extend[ed] his statutory grant by contract or agreement," *Masonite*, 316 U.S. at 277, must consider whether the patentee has eliminated the possibility of competition by paying off rivals to give up their claims. Suppose, for example, that there is a 50-50 chance that a patent-holder will prevail in litigation to keep a particular product off the market, and thus a 50 percent chance of entry yielding immediate benefits to consumers (assuming the patent conveys market power).[11] If the patent holder and challenger enter into a settlement in which the challenger gives up the right to enter,

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[11] The Commission found, based on the special circumstances surrounding the entry of generic drugs and on the specific experience upon the introduction of a generic version of Schering's K-Dur, that delay in that introduction had substantial adverse effects on consumers, and that, under this Court's teachings in *California Dental Ass'n* v. *FTC*, 526 U.S. 756 (1999), and in *IFD*, *supra*, the presence of such effects obviates any more extensive market inquiry. Pet. App. 64a-75a. Although the court of appeals made critical reference to this portion of the Commission's opinion in passing, Pet. App. 15a-16a, it did not base its ruling on this point. Its own discussion of "competitive effects," Pet. App. 28a-35a, focused entirely on the ostensible competitive justifications for the restraints.

for the remaining term of the patent, in return for a cash payment from the patentee, consumers would lose the 50 percent chance they had of enjoying the benefits of competition. As the Commission recognized, settlements that are beneficial or neutral to consumers are certainly possible. For example, if the parties simply compromise on an entry date prior to the patent's expiration, without cash payments, the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent. Pet. App. 75a-76a.

If, however, the patent holder makes a substantial payment to the challenger as part of the deal, "absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* at 76a-77a (footnote omitted). The court of appeals rejected this reasoning as a matter of law, dismissing out of hand the notion that "the size of the payment [by the patentee], or the mere presence of a payment" should have any bearing on the antitrust analysis of an agreement of this sort. Pet. App. 34a. The court of appeals' reasoning ignores the fact that a firm "certain that a patent was valid * * * would have no incentive whatsoever to pay another firm to stay out of the market." Herbert Hovenkamp, *Antitrust Law*, ¶ 2046, at 339 (2004 Supp).

Moreover, contrary to the court of appeals' assumption, the Commission's analytical approach did not turn on "the untenable supposition that without a payment there would have been different settlements * * *, resulting in earlier entry dates." Pet. App. 17a n.15. The Commission's analysis never assumed that different settlements between the parties would necessarily have replaced those under investigation. Rather, the Commission used a *hypothetical* no-payment compromise as a benchmark to assess "'the difference between the amount of competition [resulting from the actual settlements] * * * versus the amount of competition that was likely to occur had it not been

for the payment to delay * * *.'" Pet. App. 76a (quoting expert witness). Where a patent holder makes a payment to a challenger in order to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition.[12]

The court of appeals' treatment of the settlement between Schering and ESI clearly illustrates its error. As to that agreement, the Commission assumed that Schering had paid $15 million for a purported side deal and $5 million to defray litigation costs, and did not rely on those payments. See Pet. App. 144a. The Commission pointed out, however, that there was no proffered justification for the $10 million payment -- which was expressly contingent on ESI's obtaining the FDA approval that would allow it to enter the market -- other than ESI's "adaman[cy]" that such a payment was necessary "to get ESI's agreement on settlement terms that delayed generic entry until 2004." *Ibid.* The court of appeals refused to consider the relationship between the payment and the increased likely level of exclusion, instead opining that the agreement was necessarily lawful because the patent issue remained subject to "fierce" dispute, and the settlement was "within the patent's exclusionary power," as incorrectly defined by the court. Pet. App. 28a.

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[12] For example, to return to the hypothetical patent claim with a 50 percent chance of success, if there are 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years' competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward. The court of appeals' approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee's claims.

3. The legal environment in which the parties entered into these restrictive agreements makes the court of appeals' error all the plainer. To establish the governing national policy in this area, Congress has twice addressed the matter of patent rights regarding branded and generic drugs, first in the Hatch-Waxman Act and then in the 2003 Medicare Amendments. In those enactments, it went to great lengths to encourage challenges to vulnerable patent claims, for the purpose of promoting early non-infringing generic entry. For example, Congress encouraged the early commencement of patent litigation – and linked it to the regulatory process – by defining the filing of an ANDA with a Paragraph IV certification as a "new (and somewhat artificial) act of infringement" that allows the patentee to bring suit without waiting for the generic company to enter the market. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990); 35 U.S.C. 271(e)(2).[13] The statute also affords the first ANDA applicant a period of exclusivity, as a further incentive to encouraging patent challenges. 21 U.S.C. 355(j)(5)(B)(iv). These provisions reflect Congress's recognition that many infringement claims are indeed vulnerable, and that consumers will benefit through successful challenges. Moreover, the pertinent provisions of the 2003 Medicare Amendments, which were prompted in part by the very antitrust concerns raised in this case,[14] further these congressional policies by requiring that

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[13] Furthermore, Congress gave patent holders a strong incentive to bring such patent litigation promptly, by affording them an automatic 30-month stay of FDA approval for the ANDA if (but only if) they commence suit within 45 days. 21 U.S.C. 355(j)(5)(B)(iii).

[14] See, *e.g.*, S. Rep. No. 167, *supra*, at 4 ("the industry has recently witnessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives").

parties entering into the settlement of patent litigation involving pharmaceuticals file such settlements with the Commission and the Department of Justice for review, and by imposing the added sanction of loss of any marketing exclusivity period for a generic manufacturer found to have violated the antitrust laws. See Pub. L. No. 108-173, § 1112 (Pet. App. 360a-361a); 21 U.S.C. 355(j)(5)(D)(i)(V).

The court of appeals' approach to antitrust analysis of patent settlements in the Hatch-Waxman context will vitiate these congressional enactments. Pharmaceutical companies have strong economic incentives to enter into the sort of anticompetitive agreements the court of appeals condoned in this case. In nearly any case in which a generic contemplates market entry, the profit that the generic anticipates will be well under the profit that the branded manufacturer would make from the same volume of sales.[15] Accordingly, absent antitrust constraints, it will almost always be profitable for the branded manufacturer to buy off generics by offering them as much or more than they would make by entering, thus securing continued exclusivity and the continued ability to charge monopoly prices.[16] Furthermore, by setting such a high bar for a showing that a patentee has exceeded the exclusionary power of the patent, the court of appeals' ruling would make Congress's recent directive that drug patent settlements be reported to the antitrust enforcement agencies for review a pointless gesture.

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[15] See *CBO Study*, at xiii (generic versions cost on average 25 percent less than original brand-name drugs at retail prices); *id.* at 28 (wholesale price of generic drugs about half that of brand-name drugs in the first year after generic entry).

[16] In the majority of past instances of such agreements, competition was barred for the *entire* nominal duration of the patents. See *FTC Generic Drug Study* at 31.

The inconsistency between the court of appeals' ruling and congressional policy is especially clear in the court's treatment of the ostensible competitive benefits of patent settlements. See Pet. App. 29a-35a. The court invoked the general public policy preference for the settlement of litigation, citing the prospect of cost savings and the achievement of "certainty" regarding patent rights. *E.g., id.* at 29a, 30a, 33a. The court noted that the Hatch-Waxman Act altered the bargaining positions of the respective parties, and may make a conventional settlement more difficult to reach in some cases. *Id.* at 31a. In fact, the court's dire warnings that the Commission's approach would impede settlements (*id.* at 34a) are entirely unwarranted. As the Commission recently reported, pursuant to Congress's directive in the 2003 Medicare Amendments, legitimate patent settlements continue to occur without hindrance from the Commission decision, using means other than payments by the patent holders to reach a compromise.[17]

More important, the court of appeals drew entirely the wrong lesson from Congress's modification of the respective rights of patent holders and challengers in the pharmaceutical context. Congress made those changes for the very purpose of benefitting consumers by fostering successful challenges and permitting early entry of non-infringing generics. The court of appeals' ruling nullifies this congressional choice, for no discernible public gain, by excusing otherwise unlawful collusive actions in order to allow the patent holder to "realize[] the full potential of its infringement suit." *Ibid.* The court of appeals' ruling, avowedly "reflect[ing] policy," *id.* at 35a, flatly contradicts the policies of Congress.

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[17] See Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004 - A Report by The Bureau of Competition* (Jan. 7, 2005), <www.ftc.gov/os/-2005/01/050107medicareactrpt.pdf>.

II. REVIEW IS NEEDED TO ENSURE UNIFORMITY ON AN ISSUE OF EXCEPTIONAL NATIONAL IMPORTANCE.

Review of the foregoing issue is needed not only because of disarray among the lower courts on this issue, but because of the dramatic impact the present ruling could have on U.S. consumers. Another court of appeals appears to have taken a strikingly different approach, ruling that it may be per se unlawful for a patent holder to "bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor * * * to stay out of the market." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (footnote omitted), *cert. denied sub nom. Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (Oct. 12, 2004). Although a number of circumstances made that interlocutory case a poor vehicle for plenary consideration of the issue,[18] the present case comes to the Court on a full record. Moreover, the ruling below has sharpened the tension between the Sixth and Eleventh Circuits. See *supra*, at 14-16.

Practical considerations magnify the impact of the ruling below on law enforcement in this area. The Commission has brought a number of administrative cases challenging pharmaceutical patent settlements, all of which except the present one

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[18] As the United States pointed out in an amicus brief in which the Commission joined, the *Cardizem* ruling was not only interlocutory but involved an unusual fact pattern involving an "interim" settlement that precluded entry during patent litigation but did not bring that litigation to an end. See Brief for the United States As Amicus Curiae, at 7, 15-18, *Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (*certiorari denied* Oct. 12 2004). Moreover, the *Cardizem* court's reference to the possibility that the agreement there extended to non-infringing products, 332 F.3d at 908 n.13, cast doubt on the reach of its per se rule.

led to the entry of consent orders.[19] Yet, because the Commission's administrative decisions are reviewable in any circuit in which the respondent resides or does business, 15 U.S.C. 45(c), any substantial pharmaceutical company involved in a future case of this sort could presumably obtain review in the Eleventh Circuit to take advantage of the ruling below without running the risk of a conflicting ruling from another circuit.

The economic implications of the court of appeals' ruling, which invites collusive arrangements between branded drug companies and generic challengers, are staggering. American consumers and health plans spend over a hundred billion dollars on prescription drugs each year.[20] In recent years, facilitated by the incentive structure of the Hatch-Waxman Act, numerous generic manufacturers have successfully challenged listed patents and entered prior to the expiration dates of those patents. See *FTC Generic Drug Study*, at 19-20 (generics prevailed in cases involving 73 percent of challenged drug products). Successful challenges have included a number of "blockbuster" drugs with annual sales in the billions of

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[19] *Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (April 14, 2003); *Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001); *Geneva Pharms., Inc.*, FTC Dkt. No. C-3946 (May 22, 2000); *Abbott Labs.*, FTC Dkt. No. C-3945 (May 22, 2000).

[20] In 2002 alone, for example, Americans spent over $160 billion for prescription drugs. See The Henry J. Kaiser Family Foundation, *Prescription Drug Trends*, at 1 (Oct. 2004). Retail prescription prices have increased an average of 7.4 percent annually from 1993-2003, almost triple the average inflation rate of 2.5 percent during that same period. *Ibid.*; see also Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures, 2003*, at 1 (January 11, 2005) (prescription drug spending rose 14.9 percent in 2002 and 10.7 percent in 2003). They are projected to increase at an even higher average rate over the next decade (10.7 percent annually between 2004 and 2013). *Prescription Drug Trends* at 2. For the past two decades, spending for prescription drugs has been the fastest growing component of the national healthcare spending. *Id.* at 1.

dollars.[21] The entry of generic drugs into such markets invariably results in dramatically lower prices for consumers and health care payors.[22] There is every indication, moreover, that this process has the potential to continue to provide consumer benefits. Of the twenty top-selling prescription drugs in the United States today, eleven, with annual sales of nearly $25 billion, currently are the subject of litigation by generic firms seeking to enter the market under the terms of the Hatch-Waxman Act.[23] The prospect of consumer benefit from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. Under the court of appeals' ruling, however, the parties in such cases will have the strong economic incentive discussed above to enter into settlements that share the benefits of continued monopoly prices and

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[21] See, *e.g.*, *SmithKline Beecham Corp.* v. *Apotex Corp.*, 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming the antidepressant Paxil held invalid); *Astra Aktiebolag* v. *Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom. In re Omeprazole Patent Litig.*, 84 Fed. App. 76 (Fed. Cir. Dec. 11, 2003) (generic manufacturer did not infringe patents claiming anti-ulcer drug Prilosec); *Eli Lilly & Co.* v. *Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid).

[22] See *CBO Study*, at ix (consumers saved roughly $8-10 billion by purchasing generic equivalents of brand-name drugs in 1994 alone); Food and Drug Administration, *Savings from Generic Drugs Purchased at Retail Pharmacies* (May 3, 2004) (patients can save up to 52 percent in prescription drug costs by purchasing generic versions of brand-name drugs).

[23] See Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2004* (Feb. 21, 2005), <http://www.drugtopics.com> (listing top-selling drugs). SEC filings and public statements by the manufacturers of the twenty top-selling drugs indicate that the following eleven drugs are subject to litigation by generic rivals: Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax, and Risperdal. See, *e.g.*, Pfizer Inc., *Form 10-Q* (Aug. 8, 2005); Wyeth, *Form 10-Q* (Aug. 5, 2005); Purdue Pharma, L.P., *Press Release* (June 8, 2005).

deprive consumers of the benefit of low-cost, non-infringing generic drugs.

III. THE COURT OF APPEALS GROSSLY MISAPPLIED THE SUBSTANTIAL EVIDENCE STANDARD.[24]

This case is also one of the rare instances in which the Court should intervene to correct a gross misapplication of the "substantial evidence" standard of review. Although the task of determining whether substantial evidence supports agency findings is ordinarily left to the courts of appeals, see *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 491 (1951), this Court has not hesitated to intervene when a court's misapprehension or, as in this case, gross misapplication of the standard threatened the effective application of the antitrust laws. See, *e.g.*, *IFD*, *supra*.

Section 5 of the Federal Trade Commission Act provides that "[t]he findings of the Commission as to the facts, if supported by evidence, shall be conclusive." 15 U.S.C. 45(c). This language has long been understood to apply the "substantial evidence" test of the Administrative Procedure Act, 5 U.S.C. 706(2)(E). See *IFD*, 476 U.S. at 454. The test is whether the Commission's findings are supported by "such relevant evidence as a reasonable mind might accept as adequate," *ibid.* (quoting *Universal Camera*, 340 U.S. at 477), not whether the reviewing court, "'mak[ing] its own appraisal of the testimony, picking and choosing for itself among uncertain and conflicting inferences,'" would reach the same conclusion.

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[24] Question 2 of the Petition, addressed in this part, applies only to the agreement between Schering and Upsher. No such factual dispute exists with respect to the agreement between Schering and ESI. Accordingly, regardless of whether review is granted on this question, review of Question 1 is nevertheless appropriate in light of the gravity of the court of appeals' error and the great importance of the issue.

IFD, 476 U.S. at 454 (quoting *FTC* v. *Algoma Lumber Co.*, 291 U.S. 67, 73 (1934)).

As explained above, the pivotal factual issue regarding the Upsher agreement was whether the $60 million payment was, in substantial part, a *quid pro quo* for Upsher's agreement not to compete until 2001, rather than an up-front, unconditional "royalty" for the product licenses that Schering obtained. The Commission examined this issue in great detail, Pet. App. 92a-141a, focusing on a license for a niacin product that the parties acknowledged was the primary item of supposed value. See *id.* at 108a n.83. The court of appeals' discussion reflects a consistent refusal to accord any weight to the reasoned conclusions of the agency entrusted with adjudicating these matters. See 15 U.S.C. 45(b). The court begins, for example, by impugning expert testimony on which the Commission did *not* rely, on the premise that the Commission's conclusions were "curiously" similar. Pet. App. 22a-24a. Then, the court dismisses the evidence upon which the Commission did rely, but entirely ignores the Commission's own explication of the record. For example, the court chastises the Commission's "non-expert opinion that Schering should have done more due diligence" in its evaluation of the niacin product. *Id.* at 24a. But the Commission's conclusions were based on no such second-guessing, but rather on the *inconsistency* between Schering's actions here and its own actions in assessing a similar commercial opportunity presented by a company that did not threaten it with generic competition. *Id.* at 108a-111a, 122a-130a.[25] Moreover, the court of appeals simply ignored the

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[25] The other product was clinically similar, and evidence showed that it presented a less risky opportunity, having already received clinical approval by the FDA. See Pet. App. 111a-116a. Schering declined to offer any up-front payment for that product, after detailed investigation. *Id.* at 116a-117a. By contrast, Schering purported to assign a high value to Upsher's unapproved product, following a more cursory investigation, and despite the

most damning, contemporaneous, and documentary evidence on which the Commission relied.[26] And, although the court of appeals made the conclusory holding that the evidence supporting its view was "overwhelming," *id.* at 25a, 26a, it cited to no such evidence.

Two aspects of the court of appeals' analysis are particularly troubling, and plainly at odds with this Court's teachings regarding appellate review of agency findings. First, the court below criticized the Commission's recognition of the economic motivations facing Schering and Upsher in drawing inferences about the $60 million payment. See *id.* at 23a-24a. But agencies are allowed to draw on their familiarity with the subject matter entrusted to them by Congress. See generally *Dickinson* v. *Zurko*, 527 U.S. 150, 160-161 (1999) (discussing reasons for deference to agency factfinding). Business practices and the economic incentives facing businesses are at the heart of the FTC's institutional expertise, and, as this Court has recognized, the Commission is entitled to rely on "common sense and economic theory" in its administrative adjudications. *IFD*, 476 U.S. at 456. Second, the court of appeals erred in deferring to the "credibility" determinations of the ALJ, rather than to the Commission's findings. Pet. App. 25a. This Court has instructed that the substantial evidence "standard is not modified in any way when the [agency] and its examiner disagree," *Universal Camera*, 340 U.S. at 496. The present circumstances underscore the wisdom of that principle. The finding at issue was not a simple fact such as who had said

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fact that the contract contained no commitment by Upsher to carry through in obtaining approval. *Id.* at 122a-130a.

[26] The Commission had relied, for example, on the terms of the agreements themselves, Pet. App. 93a-94a, and on Schering's presentation to its board of directors, which explained that the payments represented lost revenue for the period Upsher stayed off the market, *id.* at 97a n.78.

what at a particular meeting, but the broader question whether Schering and Upsher had entered into the side licensing agreement as an end in itself or in order to facilitate (and perhaps mask) large payments intended to keep Upsher out of the market. While the testimony of Schering executives is relevant to the inquiry, as the Commission acknowledged, Pet App. 96a n.77, its plausibility must be weighed against the entire record. The Commission is the body entrusted by Congress with making such determinations. On *de novo* review, the Commission unanimously disagreed with the ALJ's factual determination, and its final ruling was entitled to deference. The court of appeals' analysis shows that it failed to afford such deference.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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No. 05-273

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORPORATION AND
UPSHER-SMITH LABORATORIES, INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. Whether the Court of Appeals' application of the "substantial evidence" standard warrants this Court's rare intervention, where the Court of Appeals correctly stated the standard to be applied, said it was applying that standard, and detailed its reasons for finding that, on a review of the whole record, the Commission's findings were not supported by substantial evidence, and where the factual question at issue is one in which the agency has no expertise.

2. Whether a settlement of patent litigation between a pharmaceutical patent-holder and an alleged generic infringer that enabled generic entry years before patent expiration is an unreasonable restraint of trade simply because the settlement included a payment to the alleged infringer, regardless of the merits of the patent infringement claims and without any proof that some "better" settlement would have been achieved without a payment.

CORPORATE DISCLOSURE STATEMENTS

Pursuant to Rule 29.6 of the Rules of the Supreme Court of the United States:

Respondent Schering-Plough Corporation hereby advises the Court that:

(1) Schering-Plough Corporation has no parent corporation; and

(2) No publicly held company owns 10% or more of the stock of Schering-Plough Corporation.

Respondent Upsher-Smith Laboratories, Inc. hereby advises the Court that:

(1) Upsher-Smith Laboratories, Inc. has no parent corporation; and

(2) No publicly held company owns 10% or more of the stock of Upsher-Smith Laboratories, Inc.

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STATEMENT OF THE CASE

1. Introduction

This petition for a writ of certiorari arises out of the Federal Trade Commission's program of challenging pharmaceutical patent-infringement litigation settlements entered into in the 1990s where 1) the settlement included a payment from the patent holder to the alleged infringer and 2) the alleged infringer agreed to stay off the market for some portion of the remaining life of the patent.

In this case, the Federal Trade Commission ("Commission") challenged the settlement of two different patent-infringement lawsuits brought by Schering-Plough Corp. ("Schering"): one against Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), and one against ESI Lederle Inc. ("ESI"). In each settlement, the parties compromised on a market entry date, permitting the alleged infringer to enter the market long before patent expiration. Both the Commission's Administrative Law Judge ("ALJ") and the Court of Appeals found that the Commission's challenges lacked any merit. The Commission seeks a writ of certiorari to review the Court of Appeals' decision.

This case is an exceedingly unappealing candidate for review by this Court, for several reasons.

A. The Commission lost its challenge to the principal settlement involved in this matter—the Schering/Upsher-Smith settlement—because of the Commission's inability to prove as a factual matter that there was a net "payment." As part of that settlement, Schering paid Upsher-Smith $60 million for rights to Niacor-SR, a cholesterol treatment drug that Upsher-Smith was developing, and several other Upsher-

Smith products. Niacor-SR was in no way involved in the patent suit. The Commission conceded that if the $60 million payment was a *bona fide* fair-value payment for the rights to Niacor-SR and the other products, then its case failed. Both the Commission's ALJ, who presided over the ten-week trial, and the Court of Appeals ruled against the Commission on this threshold fair-value question. This was a pure fact issue, and it is not suitable for review by this Court.

Nor does the Commission's challenge to the settlement of the Schering/ESI suit even remotely warrant review by this Court. The Commission introduced very little evidence about the ESI settlement at trial, and acknowledged in its decision that, "as a matter of prosecutorial discretion, we might not have brought a stand alone case based on such relatively limited evidence." Pet. App. at 145a. The ESI settlement was the product of fifteen months of court-supervised mediation. The relatively small payment of $15 million was agreed to at the urging of the United States Magistrate Judge who functioned as the mediator. The expert testimony showed that Schering had an extremely strong patent case, and that the compromise entry date agreed to in the settlement fairly reflected the strength of that case. And, as the Court of Appeals observed, "[t]he FTC did not rebut this testimony, but rather ignored it." Pet. App. at 27a.

B. The Commission's claim that the Court of Appeals *misapplied* the standard of review of administrative agency fact finding does not raise a cert-worthy issue. The Court of Appeals fully, faithfully and correctly articulated the applicable standard of review in accordance with this Court's pronouncements in *Universal Camera v. NLRB*, 340 U.S. 474 (1951). This Court does not generally review claims that a "properly stated rule of law" was misapplied. *See* SUP. CT. R. 10.

C. The Commission's petition greatly overstates the extent to which the Court of Appeals' antitrust analysis differs from its own. The Court of Appeals, the Commission, and the Department of Justice *all agree* that the payment of money as part of a patent settlement in which the alleged infringer agrees to stay off the market for a period of time is *not* a *per se* violation of the antitrust laws. This is so because the patent may confer a *lawful* right to exclude the would-be competitor from the market. Consequently, all agree that the antitrust analysis must include a comparison of the exclusionary effect of the settlement agreement with the legitimate exclusionary power of the patent. *See* Pet. at 9. The problem for the Commission is that the Court of Appeals found that the Commission did not make this comparison correctly. This finding does not raise a cert-worthy issue either.

Notably, the Commission joined the Department of Justice in urging the Court to deny certiorari in a similar pharmaceutical patent-litigation case just last term in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharmaceuticals, Inc. v. Kroger Co.*, No. 03-779 (Oct. 12, 2004). *See Brief of United States as Amicus Curiae Opposing the Petition in Cardizem/Andrx*, 2004 WL 1562075 (July 2004). In their opposition to certiorari in *Cardizem/Andrx*, the Commission and the Department of Justice urged that both the absence of a circuit split on the antitrust analysis and the recent amendments to the Hatch-Waxman Act in 2003 counseled against certiorari. This issue was not worthy of certiorari last term, and it remains unworthy of certiorari today.

D. The claim in the Commission's petition—a petition that is not joined by the Department of Justice—that the decision of the Court of Appeals will have a substantial

effect on consumers is suspect.[1] Patent settlements involving payments to the allegedly infringing generic company do not appear to be recurring. The Commission itself stated in a recent report that since 1999 "the Commission is aware of no final settlements of patent litigation in the pharmaceutical industry in which the brand paid the generic to agree not to market its product."[2]

2. The Patent Infringement Settlements

Schering owns a duly-issued patent covering the sustained-release mechanism in a potassium chloride supplement called K-Dur. That patent is valid and in effect today. It expires on September 1, 2006. Pet. App. at 50a. Notably, the active ingredient in K-Dur, potassium chloride, is widely used and unpatentable. *Id.* at 2a. Indeed, even before marketing its generic version of K-Dur, Upsher-Smith and many other pharmaceutical companies produced and marketed potassium chloride supplements used to treat the same potassium deficiency as K-Dur. Pet. App. at 165a-175a.

The Upsher-Smith Settlement

In late 1995, Upsher-Smith sought FDA approval to market a generic version of K-Dur, and Schering sued Upsher-Smith for patent infringement. After a year and a half of litigation, the parties settled the patent infringement

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[1] *See* 15 U.S.C. § 56(a)(3)(A) (2005) (requiring the Commission to consult with the Solicitor General before petitioning for certiorari).

[2] Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004—A Report by the Bureau of Competition* (Jan. 7, 2005), <www.ftc.gov/os/2005/01/050107medicareactrpt.pdf> [§ II.B].

suit in June 1997, just before trial. Pet. App. at 50a. Under the terms of the settlement, Upsher-Smith could market its generic product after September 1, 2001, but not before. Pet. App. at 194a. This compromise market entry date was five years before the date Schering's patent expires. *Because of this settlement*, Upsher-Smith's generic product has been on the market for over four years as of the date of this filing. If the parties had continued the litigation and Schering had prevailed, Upsher-Smith's product would have been excluded from the market until Schering's patent expires in September 2006. *See* Pet. App. at 20a.

As part of the settlement, Schering paid $60 million for the license rights to Niacor-SR, a sustained-release niacin product that Upsher-Smith was developing, and a bundle of other products. Pet. App. at 195a. Niacor-SR, a product in no way involved in the patent case, was the most valuable of these products.

The ESI Settlement

In late 1995, ESI sought FDA approval for a generic version of K-Dur, and Schering sued ESI for patent infringement. Pet. App. at 249a. In the fall of 1996, at the urging of the trial judge, the parties agreed to engage in court-supervised mediation. Pet. App. at 250a. United States Magistrate Judge Thomas Rueter was appointed as mediator, and he supervised numerous mediation sessions over the course of fifteen months. *Id.* Finally, in December 1997, the parties agreed on a compromise market entry date that would permit ESI to market its generic product after December 31, 2003 but not before. Pet. App. at 7a, 254a-255a. ESI still would not settle without a payment from Schering.

A settlement in principle finally was reached on January 23, 1998 in a late-night mediation session in Judge Rueter's chambers. Pet. App. at 256a-257a. Judge Rueter